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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	P	ATTORNEY DOCKET NO.
09/005, 034	01/09/98	LAW		038007/0111

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HM12/0121

EXAMINER  
BRUMBACK, B

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 01/21/99 G

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. 09/005,034	Applicant(s)	Law
Examiner Brenda Brumback	Group Art Unit 1643	

Responsive to communication(s) filed on 01/09/98 and 10/09/98

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 20-27 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 20-27 \_\_\_\_\_ is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

  
LYNETTE F. SMITH  
PRIMARY EXAMINER  
GROUP 1800

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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**DETAILED ACTION**

1. The examiner acknowledges receipt of Preliminary Amendments A and B on 01/09/98 (Papers # 2 and 3 respectively). Claims 1-19 have been canceled and new claims 20-27 have been added. Pending claims are 20-27.

*Information Disclosure Statement*

2. The examiner acknowledges receipt of the Information Disclosure Statement (IDS, Paper # 5) filed 10/09/98. A signed copy of the IDS is attached hereto; however, it fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but reference A37 listed therein (Hogan et al., 1986) has not been considered because only a copy of the cover page of the reference was provided.

*Claim Rejections - 35 USC § 112*

3. Claims 20-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 20 recites a method for “treating a body part ... such that the cosmetic appearance of the subject is altered”. It is unclear what type of “cosmetic alterations” are encompassed by the claim. While the specification contains general statements regarding facial, breast, and hip augmentation and muscle mass enhancement (pages 22-23), the meaning of “cosmetic alterations” cannot be discerned from these general statements. It is unclear what types of “alterations” would be encompassed in the instant invention.

Claims 20 and 25 recite the limitation "said composition" in claim 20. There is insufficient antecedent basis for this limitation in the claims, as claim 20 does not recite a composition, but rather recites “myogenic cells”.

4. Claims 20-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

a. Claim 1 recites “proliferating myogenic cells” for administration into a body part. The specification teaches myogenic cells suitable for transfer as including myoblasts, myotubes and/or young muscle fibers (page 13, lines 11-12). The specification also teaches that while myotubes and/or young muscle fibers can be obtained in culture by exposing confluent myoblasts to a fusion medium (page 28, lines 1-6), only myoblasts can actually be proliferated in culture. Therefore, the skilled artisan would be unable to practice the invention as claimed.

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b. Claim 1 is drawn to cosmetic alteration of a body part by proliferating myogenic cells and administering the cells into the body part. This claim encompasses treatment of humans. The art teaches that when cultured myoblasts are injected into skeletal muscle in mice, some of the cells can contribute to the formation of new muscle *in vivo*; however, the art teaches that human transfer has not been successful or at best that the results of human transfer have been controversial (see Coovert et al. 1994; page 463, column 2, first full paragraph; and Hoffman, 1993, the entire document and especially page 53 through page 54, first partial paragraph). Due to the unpredictability of the art, detailed teachings of the claimed method are required to be present in the disclosure, in order to enable the skilled artisan to practice the invention. These teachings are absent from disclosure, as the disclosure only teaches myoblast transfer into mice. Also, while the art teaches partial restoration of dystrophin levels in mice injected with myoblasts, it does not teach any resulting alteration in the "cosmetic appearance" of the muscle (see Hoffman 1993, page 52, columns 1 and 2 and Coovert et al. 1994, page 463, column 2). Once again, in light of the unpredictability of the art, detailed teachings of the claimed invention are required to be present in the disclosure, in order to enable one of skill in the art to practice the claimed invention.

c. Claim 21 recites alteration of the cosmetic appearance of a body part which is a "face, breast, hip, or non-diseased muscle". The art teaches that damaged myofibers are repaired *in vivo* by the fusion of myoblasts derived from satellite cells (see Hoffman 1993, page 49, column 2, second full paragraph). The art also teaches that studies in mice have shown that injected

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myoblasts contribute to the formation of new muscle *in vivo* by fusing with endogenous myoblasts (see Coover et al. 1994). Therefore, conventional wisdom teaches that myoblasts only fuse with myoblasts (*i.e.* muscle cells). The art does not teach fusion of myoblasts with other cell types, such as adipocytes or osteocytes. Thus it is unclear how administration of myoblasts to breast tissue (which is composed of adipose tissue) or to a hip (which is composed of bone) could be used to alter the cosmetic appearance of the breast or hip. Because the art does not recognize fusion of myoblasts with adipocytes or osteocytes, detailed teachings of the claimed method are required to be present in the disclosure, in order to enable the skilled artisan to practice the invention. No such teachings are present. Furthermore, the art teaches that the growth or regenerative state of the muscle into which myogenic cells are transferred affects the degree to which donor myoblasts contribute to new muscle formation, with incorporation occurring in regenerating muscle to a much greater extent than in normal uninjured or non-diseased muscle (see DiMario et al. 1992, page 333, in its entirety). Given this teaching, it is unclear how donor myoblasts could be used to alter the appearance of non-diseased muscle. Once again, the detailed teachings necessary to overcome conventional wisdom, as taught in the art, are not found in the disclosure.

d. Claim 20 recites proliferating myogenic cells and administering the proliferated cells into a subject. The art teaches that injection of proliferating undifferentiated muscle cells results in the formation of tumors at the site of injection (see Morgan et al. 1992, page 779, the

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abstract and column 2, first full paragraph). Given this teaching, one of skill in the art would be unable to practice the invention as claimed.

e. Finally, claim 26 recites proliferated MHC-1 deficient fat cells. The instant specification teaches a method of obtaining MHC-1 deficient myoblasts and proliferating them, but does not teach how to obtain or proliferate MHC-1 adipocytes. The art does not teach methods for obtaining MHC-1 deficient adipocytes, nor does it teach methods of proliferating adipocytes. Therefore, one of skill in the art would be unable to practice the invention as claimed.

***Double Patenting***

5. Claims 20-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-11 of copending Application No. 09/005,035 . Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to methods for altering the appearance of a body part; to MHC-1 antigen-deficient myoblasts; and to controlling cell fusion through administering chondroitin sulfate with the myoblasts.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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***Conclusion***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Lynette Smith whose telephone number is (703) 308-3909. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1643 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1643 FAX telephone number is (703)-305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

Brenda Brumback  
January 19, 1999